UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,641	09/29/2003	Jong Kil	A03P1068	4692

36802 7590 01/20/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,641	KIL ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-29-03, 1-2-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1–15, drawn to an implantable cardiac stimulation device, classified in class 607, subclass 4.

II. Claims 16–17, drawn to a method, classified in class 607, subclass 6.

III. Claims 18–20, drawn to an implantable cardiac stimulation device, classified in class 607, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group II (process) and Groups I and III (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus not requiring delivery of therapy, but rather used solely to diagnose atrial flutter.

3. Inventions of Group I and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (Group I) as claimed does not require the particulars of the subcombination (Group III) as claimed because Group I does not require a microcontroller or

determining indications of tachycardia. The subcombination has separate utility such as not requiring separate leads, but a single lead in communication with both atria through the heart wall.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Peter Nichols on Tuesday, January 17, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1–15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16 –20 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

7. The information disclosure statement filed 29 September 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the last reference on Sheet 3 of 3 does not have a date. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission

of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

8. The drawings are objected to under 37 CFR 1.83(a) because they fail to show on page 4/8 "in state 212 that the left atrial rate is approximately equal to the right atrial rate" as described in the specification on page 25 in paragraph [0081] lines 1–2. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

The drawings are also objected to because on page 7/8 in Fig. 6, it is unclear what the middle waveform represents. The specification did not specifically describe the middle waveform. It is suggested to label the waveform for clarity. Similarly, on page 8/8, the waveforms are not labeled in a manner that is clear and that enables one to understand what each represents as described in the specification (i.e.; the initial portion of the waveform as described in the specification on page 28 in paragraph [0090] lines 6–5). Again, it is suggested to label the waveforms as described in the specification for clarity.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Specification

9. The disclosure is objected to because of the following informalities: On pages 13 (paragraphs [0041] and [0042]) and 23 (paragraph [0076]) Fig 4 is referenced. The drawings do not contain Fig. 4.

On page 25 in paragraph [0079], the specification refers to "as previously described in state 216" (line 4). State 216 is not previously described anywhere in the specification.

On page 28 in paragraph [0090], reference is made to "lead ll configuration" (lines 4–5). (NOTE: Examiner is not sure what the two parallel lines are in the specification; ll is used merely as an identifier to point out the informality.) What is the lead ll configuration? Where else is it referenced in the specification? This is the only place in the specification that refers to this configuration as such.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 1–15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations "the source" in lines 16 and 18, "the atrial flutter" in line 16 and "the pulse generator" in line 17. There is insufficient antecedent basis for these limitations in the claim. Additionally, the terms "one or more sensors" and "the at least one sensor" are vague. The terminology used is different for the terms and it is unclear if they are the same. Furthermore, the term "therapeutic stimulation" is vague. The word "the" or "said" should be used in front of "therapeutic", since "therapeutic stimulation" is used in line 5.

Claim 2 recites the limitation "the left and right atrial flutter" in lines 3–4. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitations "the common flutter event" in line 3, "the atrial flutter" in lines 7–8 and "the atrial flutter therapeutic stimulation" in line 8. There is insufficient antecedent basis for these limitations in the claim.

In claim 4, the phrase "are determined as the inverse of the interval" is vague. It is unclear if the processor or some other element is doing this.

In claim 5, the phrase "then induces the application ... stimulation to the heart" is unclear. It is unclear what element provides the defibrillation stimulation. Is it the processor or the implantable medical device?

Claim 6 recites the limitations "the atrial flutter" in line 7 and "the targeted atrial flutter therapeutic stimulation" in line 8. There is insufficient antecedent basis for these limitations in the claim. Additionally, "a threshold" is inferentially included. It cannot be determined if this

element is being positively recited or functionally recited. To positively recite claim the element, it is suggested to first positively recite the element.

In claim 7, it is unclear what element is providing the threshold.

Claim 8 recites the limitation "the atrial flutter therapeutic stimulation" in lines 1–2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "the atrial flutter therapeutic stimulation" in lines 2–3. There is insufficient antecedent basis for this limitation in the claim. Additionally, in the phrase "wherein at least ... stimulation is programmable" it is unclear to what element it is programmable.

Claim 10 recites the limitation "the atrial flutter therapeutic stimulation" in lines 1–2. There is insufficient antecedent basis for this limitation in the claim. Additionally, in the phrase "wherein the atrial ... is applied synchronously" is vague. It should state what element applies it synchronously.

In claim 11, "of appropriate therapeutic stimulation to" is inferentially included.

Claim 12 recites the limitation "the frequencies" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the frequency" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1–3, 5–6, 8, and 10–15 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt, U.S. Patent, 6,442,425.

Alt discloses a left atrial lead adapted to be implanted within a patient so as to provide therapeutic stimulation to the left atrium (Fig. 1); a right atrial lead adapted to be implanted within a patient so as to provide therapeutic stimulation to a right atrium (Fig. 1); one or more sensors that are collectively operative to sense activity associated with a left and right atria and to provide left and right atrial signals indicative thereof (Fig. 1); and a processor in electrical communication with the at least one sensor and that receives signals from one or more sensors (Fig. 1), wherein a processor is operative to evaluate frequencies of left and right atrial signals (column 11, lines 52–56) and, if one of the left and right signals has a higher frequency, the processor is capable of determining the atrium with the higher frequency to be the source of the atrial flutter (Fig. 2; column 8, lines 27–33; column 11, lines 58–67, 1–11, and 13–16), wherein a processor is operative to control a pulse generator to initiate delivery of therapeutic stimulation via a left or right atrial lead to an atrium determined to be a source of atrial flutter (Figs. 1–4; column 11, lines 44–51, 64–67, 1–2, and 13–16); a memory in which left and right atrial signals can be stored for subsequent evaluation by a processor to determine the source of origin of a left and right atrial flutter (Figs. 2–3); a processor is capable of initially evaluating frequency and timing characteristics of the left and right atrial signals to determine a source of origin of a common flutter event and, if neither a frequency nor timing indicates a source of origin, a processor evaluates a stored left and right atrial signals to determine which atrium signal exhibited an initial flutter event and a processor determines the atrium having an initial flutter

event as a source of an atrial flutter and applies an atrial flutter therapeutic stimulation to that atrium (Fig. 2; column 9, lines 41–56); a processor is capable of evaluating respective frequencies of left and right atrial signals and, if respective frequencies exceed a pre-selected threshold, a processor determines that a respective atrium is in fibrillation and then induces an application of an atrial defibrillation therapeutic stimulation to a heart (Fig. 3; column 9, lines 28–40); a processor evaluates the relative timing of left and right atrial signals (Figs. 1–2; column 8, lines 47–56) and, if the timing of one of the atrial signals precedes the other atrium signal by a threshold amount less than an interval between flutter events in one or more preceding cycles for a plurality of determined flutter events, then a processor is capable of determining the atrium corresponding to the atrium signal having the less preceding flutter events to be the source of the atrial flutter and induces the delivery of a targeted atrial flutter therapeutic stimulation to that atrium (Fig. 2; column 3, lines 1–4;column 8, lines 27–33; column 9, lines 41–53); wherein atrial flutter therapeutic stimulation comprises a plurality of successive electrical pulses applied via at least one of the left and right atrial leads (column 2, lines 1–4; column 5, lines 2–6; column 11, lines 64–67; column 12, lines 4–6); atrial flutter therapeutic stimulation is applied synchronously with respect to at least one of the sensed left and right atrial signals (column 2, lines 33–42; column 4, lines 18–21; column 10, lines 42–45; column 11, lines 20–24, 26–29, and 34–39); at least one ventricle lead and at least one sensor that senses activity in at least one ventricle (Fig. 1) wherein a processor induces the delivery of appropriate therapeutic stimulation to at least one of the ventricles of a patient's heart (column 5, lines 2–11); means for sensing comprises electrodes implantable in a patient's heart for communication with

the left and right atria (Fig. 1); means for sensing comprises at least one sensor implantable in the patient's heart (Fig. 1).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 4, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claims 1, 6 and 8 above, and in view of Limousin et al., U.S. Patent 5,584,867.

Alt does not disclose a threshold comprises flutter events of one atrium depolarization preceding the flutter event of the other atrium depolarization in a current cycle by an amount less than 40 percent of an interval between flutter events in one or more preceding cycles (claim 7). However, Limousin discloses a threshold comprises flutter events of one atrium depolarization preceding the flutter event of the other atrium depolarization in a current cycle (column 3, lines 9–16; column 6, lines 57–64) to provide appropriate discrimination allowing the pacemaker to

avoid confusing a wave doublet from the same atrial depolarization wave front with consecutive atrial depolarization signals (column 3, lines 33–37).

Limousin does not disclose in a current cycle by an amount less than 40 percent of an interval between flutter events in one or more preceding cycles. However, it would have been an obvious matter of engineering design choice to a person having ordinary skill in the art at the time the invention was made to modify the cycle amount criterion, as set forth in the claim, since it is held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA) 1980). See MPEP 2144.05

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the inventions of Alt and Limousin to include a threshold comprises flutter events of one atrium depolarization preceding the flutter event of the other atrium depolarization in a current cycle by an amount less than 40 percent of an interval between flutter events in one or more preceding cycles to provide appropriate discrimination allowing the pacemaker to avoid confusing a wave doublet from the same atrial depolarization wave front with consecutive atrial depolarization signals.

Alt discloses at least one of an amplitude, pulse width, interpulse interval, and number of pulses applied for the atrial flutter therapeutic stimulation (column 8, lines 47–51) but not that it is programmable (claim 9). Limousin, however, discloses at least one of an amplitude, pulse width, interpulse interval, and number of pulses is programmable (Fig. 1; column 5, lines 38–42) to provide appropriate discrimination allowing the pacemaker to avoid confusing a wave doublet from the same atrial depolarization wave front with consecutive atrial depolarization signals.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Alt to include at least one of an amplitude, pulse width, interpulse interval, and number of pulses is programmable, as taught by Limousin to provide appropriate discrimination allowing the pacemaker to avoid confusing a wave doublet from the same atrial depolarization wave front with consecutive atrial depolarization signals.

Regarding claim 4, Alt does not disclose frequencies of left and right atrial signals are determined as the inverse of the interval between detected left and right atrial deploarizations. However, it is well known in the art to use heart rate (inverse of the interval) instead of interval/cycle length, since they are functional equivalents that both equally indicate the condition of the heart.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Alt to include frequencies of left and right atrial signals are determined as the inverse of the interval between detected left and right atrial deploarizations to correctly indicate the condition of the heart.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
January 18, 2006
18 January 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/19/6